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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,686	11/02/2001	Susan Mary Kingsman	674523-2012	4344

20350 7590 03/21/2005

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

60

<b>Office Action Summary</b>	<b>Application No.</b> 10/016,686	<b>Applicant(s)</b> KINGSMAN ET AL.	
	<b>Examiner</b> Larry R. Helms	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.  
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 52-54, 57, 60-66 and 68 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☒ Claim(s) 57 is/are allowed.  
 6) ☒ Claim(s) 52-54, 60-66 and 68 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> .               |

### **DETAILED ACTION**

1. Claim 60 and 66 have been amended in the amendment of 1/24/05.
2. Claims 52-54, 57, 60-66, 68 are pending and under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. The following Office Action contains some NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

5. All previous rejection have been withdrawn.

### ***Claim Objections***

6. Claim 53 is objected to because of the following informalities: Claim 53 recites the isolated nucleic acid having the sequence set forth in SEQ ID NO:1. SEQ ID NO:1 is a protein sequence not a DNA sequence . Appropriate correction is required.

### ***The following are NEW GROUNDS of rejections***

#### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 52-54, 60-66, 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is in two parts, one for the term "5T4" antigen and one for DNA that hybridizes to claim 54 (claim 60).

The first part applies to the term "5T4" antigen and the antibody of SEQ ID NO:1. This antibody only binds to the human "5T4" antigen and there is no other "5T4" antigen except the canine of SEQ ID NO:14 described in the specification. There is no indication that SEQ ID NO:1 would bind to the canine antigen. Thus, the specification only describes an antibody that binds to the human antigen and not all "5T4" antigens as encompassed in the claims.

There is insufficient written description encompassing "5T4 antigen" because the relevant identifying characteristics of the genus such as structure of other physical and/or chemical characteristics of the "5T4 antigen" are not set forth in the specification as-filed, commensurate in scope with the claimed invention. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry,

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whatever is now claimed." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddles v. Baird, 30 USPQ2d 1481, 1483. In Fiddles v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the absence of structural characteristics that are shared by members of the genus of "5T4 antigen"; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

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Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The second part of the rejection is because of claim 60 and the broadness of any DNA that hybridizes to SEQ ID NO:5 or the complement. The claimed nucleic acids do not have to have any function. Thus applicants were not in possession of all of the nucleic acids encompassed by the claim. The claim is drawn to a genus of nucleic acids all of which hybridize to SEQ ID NO:5 or its complement and do not have any known function.

In the absence of structural characteristics that are shared by members of the genus of any nucleic acid that hybridizes to SEQ ID NO:5 or its complement; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1 "Written Description"

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Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 200

1.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 60, 62, 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimamura et al (US Patent 5,856,140, filed 4/96).

The claims recite a DNA that hybridizes under claimed conditions to SEQ ID NO:5 or its complement and a vector and a promoter linked to the DNA.

Shimamura et al teach a nucleotide sequence of SEQ ID NO:3 wherein nucleotides 397-482 are identical to nucleotides 31-116 of SEQ ID NO:5 (See attached sequence comparison) and the nucleotide of Shimamura et al is in a vector and has a promoter since it is a single chain antibody construct.

Although the claims recite a specific hybridization condition, it is the Examiner's position that Shimamura et al's DNA would hybridize under those condition. Since the Patent and Trademark Office does not have the facilities for examining and comparing

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the claimed nucleic acid with the nucleic acid of Shimamura et al, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed nucleic acid and the nucleic acid of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The response filed 1/24/05 has been carefully considered but is deemed not to be persuasive. The response states that "selectively hybridizing" means at a level significantly above background and cannot encompass random primers (see page 4 of response). In response to this argument, it is the examiner position that the nucleic acid of the prior art would hybridize under the recited conditions and be above background significantly. In addition, random primers were not cited as prior art.

### ***Conclusion***

11. Claim 57 is in condition for allowance.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

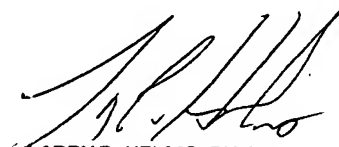


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13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 571-273-8300.

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

MOLECULE TYPE: Other nucleic acid  
FEATURE:  
NAME/KEY: CDS  
LOCATION: 1..729  
US-08-230-843-3

Query Match  
Best Local Similarity 100.0%; Pred. No. 1e-33;  
Matches 86; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

11.8%; Score 86; DB 1; Length 729;  
31 CTGGTGAAGCTGGGGCTTCAGTGAAGATATCTCGAAGGCTTCGTTACTCAATTCCT 90  
DB 397 CTGGTGAAGCTGGGGCTTCAGTGAAGATATCTCGAAGGCTTCGTTACTCAATTCCT 456  
91 GGCTACTACATGCACTGGGTGAAGCA 116  
DB 457 GGCTACTACATGCACTGGGTGAAGCA 482

RESULT 2  
US-08-636-936-3  
Sequence 3, Application US/08636936  
Patent No. 5856140

GENERAL INFORMATION:  
APPLICANT: SHIMAMURA, TOSHIRO  
APPLICANT: HAMURO, JUNJI  
APPLICANT: NAKAZAWA, HARUMI  
APPLICANT: KANAYAMA, YUKA  
APPLICANT: SUGAMURA, KAZUO  
APPLICANT: TAKESHITA, TOSHIKAZU  
TITLE OF INVENTION: IMMUNOSUPPRESSANT  
NUMBER OF SEQUENCES: 12  
CORRESPONDENCE ADDRESS:  
ADDRESSEE: OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT,  
P.C.  
STREET: 1755 S. Jefferson Davis Highway, Suite 400  
CITY: Arlington  
STATE: Virginia  
COUNTRY: U.S.A.  
ZIP: 22202

COMPUTER READABLE FORM:  
MEDIUM TYPE: Floppy disk  
COMPUTER: IBM PC compatible  
OPERATING SYSTEM: PC-DOS/MS-DOS  
SOFTWARE: Patentin Release #1.0, Version #1.25  
CURRENT APPLICATION DATA:  
APPLICATION NUMBER: US/08/636,936  
FILING DATE: 24-APR-1996  
CLASSIFICATION: 424

PRIOR APPLICATION DATA:  
APPLICATION NUMBER: US 08/230,843  
FILING DATE: 21-APR-1994  
APPLICATION NUMBER: JP 094491/1993  
FILING DATE: 21-APR-1993  
PRIOR APPLICATION DATA:  
APPLICATION NUMBER: JP 036065/1994  
FILING DATE: 07-MAR-1994

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TELEFAX: (703) 413-2220  
TELEX: 248855 OPAT UR

INFORMATION FOR SEQ ID NO: 3:  
SEQUENCE CHARACTERISTICS:  
LENGTH: 729 base pairs  
TYPE: nucleic acid  
STRANDEDNESS: double  
TOPOLOGY: linear  
MOLECULE TYPE: other nucleic acid  
FEATURE:

NAME/KEY: CDS  
LOCATION: 1..729  
US-08-636-936-3

Query Match  
Best Local Similarity 100.0%; Pred. No. 1e-33;  
Matches 86; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

11.8%; Score 86; DB 2; Length 729;  
31 CTGGTGAAGCTGGGGCTTCAGTGAAGATATCTCGAAGGCTTCGTTACTCAATTCCT 90  
DB 397 CTGGTGAAGCTGGGGCTTCAGTGAAGATATCTCGAAGGCTTCGTTACTCAATTCCT 456  
91 GGCTACTACATGCACTGGGTGAAGCA 116  
DB 457 GGCTACTACATGCACTGGGTGAAGCA 482

RESULT 3  
US-08-881-037-11  
Sequence 11, Application US/08881037  
Patent No. 6080588

GENERAL INFORMATION:  
APPLICANT: Gluck, Gary D.  
APPLICANT: Swanson, Patrick C.  
TITLE OF INVENTION: DNA BINDING ANTIBODIES  
NUMBER OF SEQUENCES: 113  
CORRESPONDENCE ADDRESS:  
ADDRESSEE: Morrison & Foerster  
STREET: 755 Page Mill Road  
CITY: Palo Alto  
STATE: CA  
COUNTRY: USA  
ZIP: 94304-1018

COMPUTER READABLE FORM:  
MEDIUM TYPE: Floppy disk  
COMPUTER: IBM PC compatible  
OPERATING SYSTEM: PC-DOS/MS-DOS  
SOFTWARE: Patentin Release #1.0, Version #1.30  
CURRENT APPLICATION DATA:  
APPLICATION NUMBER: US/08/881,037  
FILING DATE: 23-JUN-1997  
CLASSIFICATION: 530  
PRIOR APPLICATION DATA:  
APPLICATION NUMBER: US 08/443,540  
FILING DATE: 18-MAY-1995  
CLASSIFICATION: 530

ATTORNEY/AGENT INFORMATION:  
NAME: Koneki, Antoinette F.  
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REFERENCE/DOCKET NUMBER: 203442110710  
TELECOMMUNICATION INFORMATION:  
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TELEFAX: (650) 494-0792  
TELEX:

INFORMATION FOR SEQ ID NO: 11:  
SEQUENCE CHARACTERISTICS:  
LENGTH: 334 base pairs  
TYPE: nucleic acid  
STRANDEDNESS: single  
TOPOLOGY: linear  
US-08-881-037-11

Query Match  
Best Local Similarity 100.0%; Pred. No. 1.e-23;  
Matches 66; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

9.1%; Score 66; DB 3; Length 334;  
31 CTGGTGAAGCTGGGGCTTCAGTGAAGATATCTCGAAGGCTTCGTTACTCAATTCCT 90  
DB 8 CTGGTGAAGCTGGGGCTTCAGTGAAGATATCTCGAAGGCTTCGTTACTCAATTCCT 67  
91 GGCTAC 96  
DB 68 GGCTAC 73